

Applicants : SHEN, et al.
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- B1
- c) Performing the HPLC-FPS of the Radix Scutellariae extract;
- d) Determining the profile of HPLC-FPS of Radix Scutellariae extract, wherein the amounts of peaks are 4 at low limit and 5 at high limit, when the peak area is over 2.0×10^6 .
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The new claims 33 to 43 are submitted herein as Exhibit A.

REMARKS

Claims 1-4, 10, 11, 14, and 27-29 are pending in the application. The Examiner to whom this application is assigned withdrew claims 10, 14, and 27-29 from consideration. In this Amendment, Claims 4 to 32 are canceled without prejudice. The new claims 33-43 are added.

Support for new claim 33 may be found inter alia from old claim 26. Support for new claim 34 may be found inter alia from old claim 27. Support for new claim 35 may be found inter alia from old claim 28. Support for new claim 36 may be found inter alia from old claim 29. Support for new claim 37 may be found inter alia from old claim 31. Support for new claim 38 may be found inter alia from old claim 32. Support for new claim 39 may be found inter alia from old claim 4. Support for new claim 40 may be found inter alia from old claim 5. Support for new claim 41 may be found inter alia from old claim 6. Support for new claim 42 may be found inter alia from old claim 7. Support for new claim 43 may be found inter alia from old claim 8. Accordingly, there is no issue of new matters and applicants respectfully request the entry of this amendment. Upon entry, claims 1-3 and 33-43 are pending.

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The Examiner to whom the application has been assigned has restricted the invention into two groups. In response, Applicant would like to elect Group I, directed to claims 1-3 for further prosecution of the application, with traverse.

However, inventions are not Independent under MPEP §806.04(A). The Examiner has stated restriction is proper because "[I]nventions I and II are unrelated." To justify this position, he states, quoting MPEP §806.04 and MPEP §808.01, that the inventions are unrelated if it can be shown that they are not disclosed as capable of use together **and** they have different modes of operation, different functions, or different effects." (Emphasis added).

After stating this, the Examiner does not provide any factual evidence that the inventions (1) are incapable of use together or (2) they have different modes of operation, different functions, or different effects. Instead, he states the inventions "have acquired separate status" and are "separate subject for inventive effect and require independent searches" These statements are not evidence of the inventions being incapable of use together and having different modes of operation, function or effect. Indeed, the composition and the method for identifying the composition are capable of use together and have connected modes of operation, function and effect.

In conclusion, the Examiner has failed to meet either prong of the two-part showing required under MPEP §806.04 and MPEP §808.01 for independent inventions, and therefore restriction between Groups I, and II is improper.

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The Examiner has not, and cannot, demonstrate a "serious burden" because a single search can be done for both Groups: a composition (Group I) and a method for identifying a composition (Group II). Applicants respectfully contend that the Examiner has not demonstrated "a serious burden." Therefore, in view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the present restriction requirement and respectfully request the Examiner render the Office Action on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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I hereby certify that this paper is being deposited this date with the U.S. Postal Service with sufficient postage for first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Albert Wai-Kit Chan 11/25/02
Albert Wai-Kit Chan Date
Reg. No. 36,479

-- 33. (New) A composition of claim 1 comprising of about 90-180 parts of extract of Flos Lonicerae and Fructus Forsythiae, about 10-60 parts of supercritical extract of Flos Lonicerae and Fructus Forsythiae, about 30-50 parts of Radix Scutellariae extract and about 23-125 parts of excipients. --

-- 34. (New) A composition of claim 33 for preparing a product, wherein said constituents are presented in the following range: about 0.01 percent to about 99.99 percent of effective constituents, and about 99.99 percent to 0.01 percent of medical excipients. --

-- 35. (New) A composition as in claim 33, wherein said constituents are presented in the following formula: about 10 percent to 100 percent of Flos Lonicerae, 10 percent to 100 percent of Fructus Forsythiae, and 10 percent to 100 percent of Radix Scutellariae. --

-- 36. (New) A composition as in claim 33, wherein said constituents are further composed of about 1.3 percent to 1.6 percent of Chlorogenic acid, 0.2 percent to 0.3 percent of Phillyrin and about 14.1 percent to 15.3 percent of Baicalin. --

-- 37. (New) The composition of claim 2, wherein virus is herpes I virus, herpes II virus, influenza virus, parainfluenza virus or Human immunodeficiency virus. --

-- 38. (New) An antibacterial composition of claim 1. --

-- 39. (New) The composition of claim 1, wherein the Flos Lonicerae raw material is identified by the method, which comprises the steps of:

- a) Using the Chlorogenic acid as the standard and using the Flos Lonicerae raw material as a sample;
- b) Preparing the sample solution of Flos Lonicerae raw material;
- c) Performing the Fingerprint Chromatogram (HPLC-FPS) of Flos Lonicerae raw material under the following condition:

Conditions of Raw Material HPLC-FPS

Chromato- graphic Column	Protecting Column	Floating Phase	Tempera- ture	Inspector	Injectio n Volum	Run Time (min)
Inertial ODS-3,5µm 4.6mm*250mm	phenomenex C18(ODS), 4mm*3mmID	1% acetic acid solution	room tempera- ture	PDA210~400 nm whole wavelength scan	5.00µl	35

- d) Calculating the value in accordance with the following calculation formula:

$$Cx = C1 + (C2 - C1) * (Ax - A1) / (A2 - A1)$$

C1 and C2: quantities of the standard.

A1 and A2: peak areas of the standard.

Cx and Ax: quantity and peak area of the sample.

- e) The HPLC-FPS of Flos Lonicerae raw material:
The amounts of peaks are 8 at low limit and 11 at high limit, when the peak area is over 2.0×10^6 . --

-- 40. (New) The composition of claim 1, wherein the composition of Fructus Forsythiae raw material is identified by the method which comprises the steps of:

- a) Using Phillyrin as the standard, and use the Chinese Fructus Forsythiae raw material as the sample;
- b) Weighing exactly 375mg of the powder of Fructus Forsythiae raw material;
- c) Performing HPLC-FPS of Fructus Forsythiae raw material wherein the amounts of peaks are 11 at low limit and 14 at high limit, when the peak area is over 2.0×10^6 .

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-- 41. (New) The composition of claim 1, wherein the composition of the Radix Scutellariae raw material is identified by the method which comprises the steps of:

- a) Using Baicalin as the standards, and use the Chinese Radix Scutellariae as the sample;
- b) Weighing appropriate amount of Radix Scutellariae raw material and prepare the sample solution;
- c) Performing the HPLC-FPS of Radix Scutellariae raw material and calculation the value of HPLC-FPS of Radix Scutellariae's raw material wherein there are 22 peaks at low limit and 25 at high limit, when the peak area is over 2.0×10^6 . --

-- 42. (New) The composition of claim 1, wherein the composition comprising extracts of Flos Lonicerae and Fructus Forsythiae are identified by the method which comprises the steps of:

- a) Using the Chlorogenic acid and Phillyrin respectively as the standard, and use the extracts of Flos Lonicerae and Fructus Forsythiae as a sample;
- b) Preparing the sample solution of the drug substance, further comprising the steps of:
 - i) Taking some Flos Lonicerae and Fructus Forsythiae, rub it into powder and then pass the 40 item of bolt;
 - i) Weighing exactly appropriate amount of the powder and put it into the centrifuge tube;
 - iii) Adding appropriate amount of organic solvent to dissolve the extract;
 - iv) Shaking the mixture ultrasonically and take the upper solution;
 - v) Repeating the above extraction procedure if necessary;
 - vi) Washing the residue with organic solvent and combine the extract;
 - vii) Filtering the extract if necessary.
- c) Performing the HPLC-FPS of the drug substance of Flos Lonicerae and Fructus Forsythiae, under the following condition:

Conditions of HPLC-FPS of Drug Substance

Chromato-graphic Column	Protecting Column	Floating Phase	Tempera-ture	Inspector	Injectio n Volum	Run Time (min)
Inertsil ODS-3,5µm 4.6mm*250mm	Phenomene C18(ODS), 4mm*3mmID	1% acetic acid solution	room tempera-ture	PDA210-400nm whole wavelength scan	20.00µl	35

- d) Determining the peaks created by the analysis wherein the amounts of peaks are 18 at low limit and 23 at high limit, when the peak area is over 2.0×10^6 . --

-- 43. (New) The composition of claim 1, wherein the composition of the drug substance of Radix Scutellariae identified by the method which comprises the steps of:

- a) Using Baicalin as the standard solution and use the extract of Radix Scutellariae as the sample solution;
- b) Weighing exactly 20mg of the powder of Radix Scutellariae and preparing the sample solution of the extract;
- c) Performing the HPLC-FPS of the Radix Scutellariae extract;
- d) Determining the profile of HPLC-FPS of Radix Scutellariae extract, wherein the amounts of peaks are 4 at low limit and 5 at high limit, when the peak area is over 2.0×10^6 . --

The support for new claim 33 may be found from old claim 26.

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The support for new claim 39 may be found from old claim 4.

The support for new claim 40 may be found from old claim 5.

The support for new claim 41 may be found from old claim 6.

The support for new claim 42 may be found from old claim 7.

The support for new claim 43 may be found from old claim 8.